



AUDIT REPORT FOR ROMANIA

October 31 through November 14, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Romania's meat inspection system from October 31 through November 14, 2001. Two establishments certified to export meat to the United States were audited. Both of these were slaughter establishments and conducting some processing operations.

The last audit of the Romanian meat inspection system was conducted in November 2000. Three establishments were audited and two were found acceptable and one was acceptable re-review. Four major concerns were reported at that time:

1. The HACCP (Hazard Analysis Critical Control Point) plan in Establishment 2 did not adequately document the procedures of verification and monitoring of CCPs (Critical Control Points) in slaughter operation.
2. The HACCP plan did not document to ensure compliance with zero tolerance for visible fecal material on carcasses in Establishment 2.
3. The selection of carcasses for *E. coli* testing was not performed randomly in Establishments 2 and 68.
4. Maintenance program was ineffective in that it did not ensure prevention and correction of defects such as rust on chains, dirty hooks and flaking paint in coolers in Establishment 68.

Cattle and pork species and cured (dried) smoked product, cooked sausages and shelf stable canned products are eligible for export to the U.S from Romania.

During calendar year 2001, Romanian establishments did not export any meat product to the U.S.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Romanian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of records pertaining to residue control in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one

performing both; analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella* and the other performing only analytical testing of field samples for the national residue testing program

Romania's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in both establishments audited (Est. 2 and Est. 68). Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, four major concerns had been identified during the last audit of the Romanian meat inspection system, conducted in November 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected.

HACCP-implementation deficiencies and other deficiencies had been found in three establishments visited (Ests. 2, 12, and 68) in the last audit. The GOR (Government of Romania) de-listed Establishment 12 for the year 2001. During this new audit, implementation of the few required HACCP elements was not well documented in Establishment 68.

Entrance Meeting

On October 31, 2001, an entrance meeting was held in the Bucharest offices of the Food Hygiene and Public Health Directorate (FHPHD), National Sanitary Veterinary Agency (NSVA), Ministry of Agriculture, Food and Forestry (MAFF) and was attended by

Dr. Gabriel Predoi, Director General (Chief Veterinary Officer), FHPHD; Dr. Dana Tanase, Director, Food Hygiene and Public Health (Chief Meat Inspection Program); Dr. Ion Nisipasu, State Inspector, Food Inspection Program; Dr. Anca Ciuciuc, Veterinary and Public Health Inspector; and Dr. Suresh P. Singh, International Audit Staff Officer. Topics of discussion included the following:

1. Updates on the inspection system of Romania
2. The audit itinerary and travel arrangements
3. Animal diseases status in Romania according to APHIS
4. Generic *E. coli* and *Salmonella* testing
5. HACCP implementation and previous audit issues.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Romania's inspection system in November 2000 except Dr. Virgil Marcel Eftimie is now working with the European Union (EU) for Romania's access in EU. He was previously Chief, Meat Inspection Officer.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the individual establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.

- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Romania as eligible to export meat products to the United States were full-time FHPHD employees, receiving no remuneration from either industry or establishment personnel. Domestic establishments have different government oversight.

Establishment Audits

Two establishments were certified to export meat products to the United States at the time this audit was conducted. Both establishments (2 and 68) were visited for on-site audits. In Establishment 2, both FHPHD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. In Establishment 68, basic establishment facilities and condition of facilities equipment and inspection system controls were acceptable, however the establishment was not in operation because of financial problems (bankruptcy).

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories, intra-laboratory quality assurance procedures, including sample handling and methodology.

The Hygiene and Veterinary Public Health Institute (HVPHI) laboratories of NSVA in Bucharest were audited on November 1, and the microbiology laboratory in the same Institute was visited on November 2, 2001. The Director of HVPHI is Dr. Sergui Meica. The laboratories in Bucharest were accredited in 1998 by the National Accreditation Body called RENAR. The laboratory was accredited for chemical control, microbiological control and toxicological control. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent

recoveries, check sample frequency and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Arsenic in trace elements group (400) has not been tested before but, beginning in January 2002, the laboratory in Bucharest is going to start testing. All the equipment and procedures are being prepared.

Romania's microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the Hygiene and Veterinary Public Health Institute laboratory in Bucharest was audited. No deficiencies were observed in the microbiology laboratory.

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments at the time of this audit:

Establishment 2: Cattle slaughter and processing, and pork boning.

Establishment 68: No activities but approved to do: cattle, swine slaughter, boning, cured/dried/smoked products and canned products but currently not an active producer

SANITATION CONTROLS

Based on the on-site audits of establishments, Romania's inspection system had controls in place for water potability records, chlorination procedure, back siphonage prevention, hand washing facilities, establishments separation, pest control program, temperature control, lighting, operations work space, inspector work space, ventilation, facilities approval, equipment approval, over-product equipment, product contact equipment, other product areas, dry storage areas, antemortem facilities, welfare facilities, outside premises, personal dress and habits, personal hygiene practices, sanitary dressing procedures, cross contamination prevention, product handling and storage, product reconditioning, product transportation, operational sanitation and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

ANIMAL DISEASE CONTROLS

Romania's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. No cases of Bovine Spongiform Encephalopathy (BSE) have been reported in Romania. There was adequate animal identification and traceback, antemortem inspection procedures, antemortem dispositions, postmortem inspection procedures, postmortem dispositions, condemned and restricted product control, and returned and rework product control.

RESIDUE CONTROLS

Romania's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Romanian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Romanian inspection system had controls in place to ensure adequate pre-boning trim, boneless meat reinspection, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, special label claims, inspector monitoring, processing schedules, processing equipment, processing records, empty can inspection, filling procedures, container closure exam, interim container handling, post-processing handling, processing defect actions-plant, processing control-inspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

During this new audit, implementation of the few required HACCP elements was not well documented in Establishment 68.

Testing for Generic *E. coli*

Romania has adopted the FSIS regulatory requirements for *E. coli* testing.

Two establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Additionally, establishments had adequate controls in place to prevent meat products intended for Romania domestic consumption from being commingled with products eligible for export to the U.S.

Control of *Listeria monocytogenes*

The GOR inspection service has a surveillance program for ready-to-eat product for *Listeria monocytogenes* testing. This testing is mandatory if product is to be exported.

ENFORCEMENT CONTROLS

Inspection System Controls

The Romanian inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

In Establishment 68, horse slaughter for future operation is separated and done once a week in bovine section, however, the auditor requested that the GOR seek policy requirements from Washington.

Testing for *Salmonella* Species

The two establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Romania has adopted the FSIS regulatory requirements for *Salmonella* testing.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, Romania was not exempt from the species verification-testing requirement but had applied for exception with International Policy Division (IPD). The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the Romanian equivalent of Circuit Supervisors in establishments certified to export to the United States. All were veterinarians with several years of experience.

The internal monthly review program was applied only to exporting establishments. Internal review visits were both; announced in advance and sometimes not announce in advance, and were conducted, at times by individuals and at other times by a state veterinarian in a team of review, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in district offices and in the central offices of the National Sanitary Veterinary Agency in Bucharest, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to the General Director and the Director FHPHD, NSVA, for evaluation; they formulate a plan for corrective actions and preventive measures.

The GOR has provided training to field inspector on HACCP/PR and SSOP programs.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision, controls of security items, shipment security, species verification, and product entering the establishments from outside sources.

GOR inspection service has a regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* testing standard. GOR inspection service through Veterinary Police has been detecting and detaining potentially hazardous food in commerce to prevent its consumption.

The procedure for imposing sanctions and fines was established by government decision (Mr. 794/1993), which was recently modified by government decision (605/2000). These sanctions and fines are applied in the case of misdemeanor, and are imposed on the local, regional and central level. Only in the felony case, names of violators can be published. The felony cases are proceeded by court.

Exit Meetings

An exit meeting was conducted in Bucharest on November 14, 2001. The participants were Dr. Virgil Marcel Eftimie, Deputy General Director, NSVA assign to the E.U.; Dr. Dana Tanase, Director, FHPHD; Dr. Ion Nisipasu, State Inspector, FHPHD; Dr. Anca Ciuciuc, Inspector, FHPHD; Dr. Sergiu Meica, Director, the Hygiene and Veterinary Public Health Institute and Dr. Suresh P. Singh, International Audit Staff Officer. The following topics were discussed:

1. Horse slaughter in Establishment 68.
2. The HACCP program elements were discussed in Establishments 68.
3. The monitoring of CCPs, recording and verification.

CONCLUSION

The inspection system of Romania was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Two establishments were audited and both were acceptable. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Suresh Singh
International Audit Staff Officer

(signed)Dr. Suresh Singh

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (*no comments received*)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. Identified	7. Documentation done daily	8. Dated and signed
2	√	√	√	√	√	√	√	√
68	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment’s procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan’s record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. Procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment .doc. review
2	√	√	√	√	√	√	√	√	√	√	√	√
68	√	√	no	√	√	√	√	√	√	√	√	no

Intended use of finished products was not mentioned in the plan. There was no documentation of pre-shipment review.

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an Equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
2	√	√	√	√	√	√	√	√	√	√
68	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	<i>1. Testing as required</i>	<i>2. Carcasses are sampled</i>	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
2	√	√	N/A	√	√	√
68	√	√	N/A	√	√	√